SNACK FOOD
ASSOCIATION
An International Trade Association

VIA Electronic Mail and by Hand

April 2, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852
ATTN: Docket No. 02N-0278

RE: Implementing Regulations of PL 107-I 88:
Docket No. 02N-0278, Section 307 (Prior Notice)

Dear Sir or Madam:

The Snack Food Association (SFA) is an international trade association representing snack food manufacturers and suppliers. SFA business membership includes, but is not limited to, manufacturers of potato chips, tortilla chips, crackers, corn chips, pretzels, popcorn, extruded snacks, meat snacks, pork rinds, snack nuts, party mix, fruit snacks, cereal snacks, snack bars, and various other snacks. Retail sales of snack foods in the U.S. total more than $30 billion annually.

SFA strongly supports a rigorous food security system to protect the nation's food supply. Last year during Congressional debate on food security, SFA supported the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. However, we are concerned about some provisions of the draft regulations put forward in the Federal Register on February 3, 2003 to implement the Act. Specifically, SFA appreciates the opportunity to respond to the request for comments on Section 307: Bioterrorism Preparedness; Prior Notice of Imported Food Shipments.

Section 307 amends section 801 of the Federal Food, Drug, and Cosmetic Act to require prior notice of imported food shipments. The notice is required to describe the article of food, the manufacturer and shipper, the grower, the country of origin, the country from which the article is shipped, and the anticipated point of entry. A shipment of food offered for entry into the United States without prior notice is to be refused admission at least until a notice is filed.

SFA agrees that commercial business practices will need to change to accommodate the new prior notice regulations. However, we are concerned that some provisions of the proposed

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regulation will have the unintended consequence of changing trade practices to the point of being disruptive.

Date-Coded Foods. The Bioterrorism Act states that it is a prohibited act to import or offer for import an article of food without prior notice, and that food imported or offered for import without adequate prior notice will be refused admission and held at the port of entry until adequate prior notice is received, unless FDA directs its removal to a secure facility. SFA is concerned that minor technicalities and duplication of paperwork may result in unwarranted delays in food shipments. Holding foods too long at a border may jeopardize valuable shelf time and render them unfit for sale. It is possible that moving certain types of foods to a secure facility before having them released may push the limits of the date code. Further, if the prior notice is judged inadequate, how will FDA move to assure it is corrected in minimal time?

In the regulation it should be stated that a shipment with inadequate prior notice would only be held until a corrected prior notice is submitted. A target time period for such a correction should be no longer than 24 hours and should be stated in the final regulation. In order to assure the best efficiency at the border, FDA should develop a system that evaluates the prior notice and makes other admissibility determinations at the same time to be reasonably certain there will be no unnecessary delays. Unless there is efficiency and speed of processing at borders, imported food may not be fit to move to stores (too close to freshness code dates) or may even spoil.

Amendments and Updates. Under the proposed rule, amendments relating to product identity information are allowed under specified circumstances. Further, updates about arrival information are required if plans change. SFA is concerned that the amendment process lacks sufficient flexibility both in terms of load adjustment and timing. It is common practice to fill extra space in a shipment with additional product after an order has been filled. The FDA should consider allowing last minute changes in a load whether it consists of adding more of the same exact food (change in quantity) or adding similar foods in the same category, for example, adding several cases of potato chips to a truckload of corn chips (all snack foods). More flexibility is needed to avoid the extraordinary cost of importing partial shipments.

In terms of timing, all deadlines are too far in advance of anticipated arrival time, especially for trucks from Mexico and Canada. Submitting a prior notice at 12:00 noon the day before may not be practical because even at that time any plant with a great amount of trucking activity may not know what will go on a truck until almost before the truck leaves. Further, in some cases, food plants are no more than 20 minutes from the border. If amendments to prior notice are only allowed 2 hours before the transporting vehicle arrives, then the truck is left idling at the plant for the balance of the time. (i.e., 1 hour and 40 minutes). This will create a tremendous bottleneck at the manufacturing plant. The delay of trucking activities of in-coming

and out-going tractor-trailers would not only lead to congestion at the plant's loading and unloading docks, but also to costly delays. Long delays of time-sensitive products being transported in and out of the plant could possibly compromise product integrity. In terms of timing, there needs to be more flexibility in both the prior notice and the amendments in terms of timing. There is no reason why a completely new prior notice must be submitted.

Multi-Ingredient Processed Food. As required by section 801(m)(1), FDA is proposing to require the submission of the identity of all growers of each article and the growing location if different from the grower's business address, if known at the time of submission of the prior notice (proposed Sec. 1.288(g)). Further, if a product is sourced from more than one grower, the prior notice must provide the identification of all growers, if known. It is SFA's position that it would be impossible to list all growers for a multi-ingredient processed food and its seasoning components. For example, if a processed food product uses corn purchased on the open market, there is no chance of determining the grower because of the systems used by grain elevators. In this case, listing the grower would be impossible. This scenario is further compounded when finished products such as cereals and snack chips contain multi-grain ingredients. SFA understands the necessity for grower information for fresh fruits and vegetables, but it is impossible to apply the grower identification requirement to multi-ingredient processed foods.

Transparency with U.S. Customs Service. In the preamble, FDA states that it is proposing to require electronic submission of prior notice because the Agency believes an electronic system will be the least burdensome and most efficient way to implement and enforce the requirement of section 801(m) of the act. SFA agrees with this approach and applauds the FDA on seeking efficiencies for all stakeholders. FDA further states in the preamble that it is working with the U.S. Customs Service to develop an Automated Commercial Environment ("ACE") and will allow prior notice to be submitted through ACE. However, implementation of ACE is not expected before 2005. Given these circumstances, FDA and U.S. Customs agreed that to meet the statutory deadline, an FDA stand-alone, web-based electronic system to execute receipt of prior notice would be necessary until ACE is fully operational.

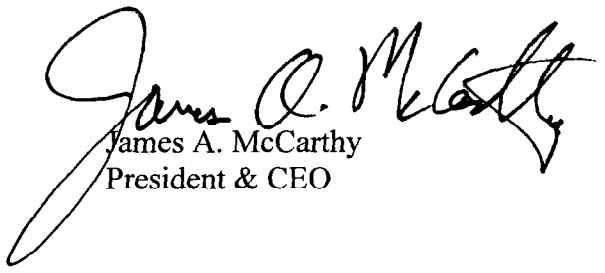
SFA is concerned that until ACE is fully operational, there may not be an efficient flow of information between FDA and U.S. Customs. This will become especially bothersome, for instance, if FDA stops a shipment and eventually directs it to a secure facility until they receive an adequate prior notice. Upon release, FDA would have to notify Customs (and the submitter) that the food was no longer being refused admission. It is imperative that discrepancies shared between FDA and Customs be resolved in an efficient manner and that clear communications between the Agencies be established so both are aware of detentions and releases in real time. To avoid any confusion, FDA should spell out the exact mechanisms for communication with Customs in the final rule.

Finally, we recognize that commercial practices will need to change to accommodate the new requirements. However, SFA is concerned that FDA may have made assumptions about business that may not be valid and may be quite restrictive. SFA suggests that FDA benchmark some of their assumptions to assure that the prior notice regulation does not change trade practices to a point of being disruptive.

We appreciate the opportunity to comment on this proposed regulation and are committed to working with FDA and all government agencies to protect the food supply.

If you have any questions, please do not hesitate to contact us.

Respectfully submitted,



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